

### **REMARKS**

Claims 1, 3, and 4 are pending in the application, with all pending claims being currently amended and claim 2 being canceled.

In the Official Action, Examiner requests that the application be reviewed for errors. In particular, the Examiner states that the names of microorganisms should be italicized or underlined and the names of genera of microorganisms should be capitalized. These errors are noted as being shown corrected in the corresponding U.S. Patent Application Publication 2004/0202749. This was discussed during a teleconference with Examiner on October 1, 2007 wherein Examiner instructed Applicants simply to refer to the publication in the present response. Accordingly, Applicants submit that the requested corrections are unnecessary. In addition, as further requested by Examiner, the claims are currently amended to conform to the standard practice of starting independent claims with --A-- and dependent claims with --The--. In conjunction therewith, the multiple dependencies in claims 3 and 4 have been deleted. To that end, each of the pending claims 1, 3, and 4 are now independent, with claims 3 and 4 further reciting the mycological characteristics of *Bifidobacterium longum* FERM BP-7877.

### **35 U.S.C. §101 rejection**

Previously pending claims 1-4 stand rejected under 35 U.S.C. §101 because the claims allegedly read on an organism per se which is found in nature and, thus, is unpatentable to Applicants. In view thereof, Examiner suggests using the language "a biologically pure culture" in connection with the *Bifidobacterium longum* FERM BP-7787 strain. See Official Action, page 2.

Applicants have adopted Examiner's suggested language in now pending independent claims 1, 3, and 4. In particular, claim 1 now recites "A biologically pure culture of *Bifidobacterium longum* FERM BP-7787", with claims 3 and 4 being similarly amended.

Accordingly, Applicants submit that this rejection is overcome and must be withdrawn.

**35 U.S.C. §112, second paragraph, rejection**

Previously pending claims 1-4 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. The Applicants have amended the claims to overcome the rejection as follows.

In claim 1, the allegedly confusing language has been deleted or modified to more clearly define the mycological characteristics of the *Bifidobacterium longum* FERM BP-7787. Claim 2 has been canceled. Claim 3 has been amended to remove the errant "3." before the term "Powder".

In view of the above, Applicants submit that this rejection is overcome and must be withdrawn.

**35 U.S.C. §112, first paragraph, rejection**

Claims 2-4 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabling to one skilled in the art. Specifically, Examiner asserts that it is not clear that the written description is sufficiently repeatable to avoid the need for a deposit of the *Bifidobacterium longum* FERM BP-7787. Further, it is allegedly unclear if the starting materials were readily available to the public at the time of the invention. In view thereof, Examiner

suggests that a declaration or averment be provided assuring that the biological deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. In addition, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description. *See* Official Action, page 3.

In view thereof, Applicants' representative attaches hereto a copy of a "Receipt in the Case of an Original Deposit" for the biologically deposited *Bifidobacterium longum* FERM BP-7787, as issued by the International Depository Authority (See Exhibit A). As clearly evidenced in that exhibit, the deposited material was accepted for deposit on October 31, 2001 under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure. As such, Applicants submit that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. In addition, the specification at paragraph [0027] has been amended to more clearly identify the deposit.

In view of the above, Applicants submit that this rejection is overcome and must be withdrawn.

### **35 U.S.C. §§102 and 103 rejections**

Examiner has rejected previously pending claims 1, 3, and 4 under 35 U.S.C. §102(b) as being allegedly anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kawashima JP58224685 ("Kawashima"). In rejecting the claims over the Kawashima reference, the Examiner states that the "reference discloses a strain of

*Bifidobacterium longum* which is resistant to low pH at least one of which appears to be identical to the presently claimed strain since it is resistant to low pH environments.” Thus, the referenced microorganism allegedly appears to be identical since it is of the same species as that of the microorganism claimed. In addition, Examiner asserts that even if the claimed microorganism is not identical to the referenced microorganism with regards to some unidentified characteristics, the differences allegedly are so slight that the referenced microorganism is likely to inherently possess the same characteristics, and, thus, the claimed strain is obvious. *See* Official Action, page 5.

It is well established that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In addition, a *prima facie* showing of obviousness is satisfied if there is a suggestion, teaching, or motivation to modify the prior art reference flowing from either the reference, the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved, and the results are expected. *KSR Int'l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

For the following reasons, Kawashima fails to teach each and every element of Applicants' invention as recited in claims 1, 3, and 4 and the Examiner has failed to establish a *prima facie* case of obviousness.

Upon review of Kawashima, the strain of *Bifidobacterium longum* disclosed in the Kawashima English abstract is M-8201, which corresponds to *Bifidobacterium longum* FERM-P

No. 6548. That strain is significantly different from Applicants' claimed *Bifidobacterium longum* FERM BP-7787. In particular, in the present specification, comparisons were made between the claimed bacterium FERM BP-7787 and the bacterium FERM P-6548. It is shown in Table 4 that FERM BP-7787 has a superior gastric acid tolerance effect as compared to FERM P-6548. For example, 23.5% of the FERM BP-7787 strain survived 2 hours at 37°C in a gastric juice environment of pH 3.0 where less than 0.01% of the FERM P-6548 strain survived these conditions. Accordingly, contrary to the Examiner's assumption, the FERM P-6548 strain does not possess the same characteristics, such as a survival rate of 10% or higher in the case of storing in artificial gastric juice of pH 3.0 at 37°C for two hours, as required by the claims. Further, the differences in the characteristics of FERM P-6548 and FERM BP-7787, as shown with the gastric acid tolerance test, are significant. Thus, FERM P-6548 is not all likely to inherently possess, or make obvious, the characteristics of Applicants' claimed FERM BP-7787. Therefore, not only does Kawashima fail to teach the *Bifidobacterium longum* FERM BP-7787, Examiner has failed to establish a *prima facie* case of obviousness based on the Kawashima disclosure.

Also in the Official Action, claims 1, 3, and 4 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Martin (1992) ("Martin").

In rejecting the claims over Martin, as with Kawashima, the Examiner states that the "reference discloses a strain of *Bifidobacterium longum* which is resistant to low pH at least one of which appears to be identical to the presently claimed strain since it is resistant to low pH

environments.” Thus, the referenced microorganism allegedly appears to be identical since it is of the same species as that of the microorganism claimed. In addition, Examiner again further asserts that even if the claimed microorganism is not identical to the referenced microorganism with regards to some unidentified characteristics, the differences allegedly are so slight that the referenced microorganism is likely to inherently possess the same characteristics, and, thus, the claimed strain is obvious. *See* Official Action, page 6. Applicants respectfully disagree for the reasons that follow.

Upon review of Martin, this reference appears to disclose four strains of *Bifidobacterium longum*, i.e., ATCC 15708 and Commercial strains 01, 03, and 07, species 3, 5, 7, and 11, respectively. With reference to Figures 1, 2, and 3 of Martin, it is indicated that the number of cells of *Bifidobacterium longum* species 3, 5, 7, and 11 that survive in yogurt, i.e., a milk base medium, on day 14 at about 4°C to 6°C is  $8 \times 10^4$ ,  $3 \times 10^6$ ,  $4 \times 10^3$ , and  $6 \times 10^5$ , respectively. Because the initial number of cells, in terms of Log CFU/g, was 7.2, 7.08, 7.2, and 7.81, respectively, as shown in Table 2 of Martin, the percent rate of survival is determined to be about 0.5%, 25%, 0.03%, and 0.9%, respectively, in accordance with the following equation:

$$\text{Survival rate (\%)} = (\text{No. surviving cells} / \text{No. initial cells}) \times 100.$$

In comparison, the survival rate of the claimed *Bifidobacterium longum* FERM BP-7787 in a milk base medium having a pH of about 4.2 on day 14 at 10°C is 51.5%, as shown in Table 3 of the specification. This survival rate is significantly higher than that of the strains disclosed in Martin. Accordingly, contrary to Examiner’s assumption, Applicants submit that the Martin microorganisms do not possess the same milk base medium survival rate characteristics

as the presently claimed microorganism. Further, the differences in the characteristics of FERM BP-7787 and the microorganisms disclosed in Martin, as shown with the low pH yogurt survivability test, are significant. Thus, the microorganisms disclosed in Martin are not all likely to inherently possess, or make obvious, the characteristics of Applicants' claimed FERM BP-7787. Therefore, like Kawashima, not only does Martin fail to teach the *Bifidobacterium longum* FERM BP-7787, Examiner has failed to establish a *prima facie* case of obviousness based on the Martin disclosure.

Finally, previously pending claims 1-4 further stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yang et al U.S. Patent No. 5,711,977 ("Yang").

Similar to Kawashima and Martin, the Examiner states that the “reference discloses strains of *Bifidobacterium longum* which are resistant to low pH at least one of which appears to be identical to the presently claimed strain (see, e.g., Tables I, II, and V) since they are all resistant to low pH environments.” Thus, at least one of the referenced microorganism appears to be identical since it is of the same species as that of the microorganism claimed. In addition, Examiner again further asserts that even if the claimed microorganism is not identical to the referenced microorganism with regards to some unidentified characteristics, the differences allegedly are so slight that the referenced microorganism is likely to inherently possess the same characteristics, and, thus, the claimed strain is obvious. *See* Official Action, pages 6 and 7. Applicants respectfully disagree for the reasons that follow.

Upon review of Yang, this reference appears to describe the following strains of *Bifidobacterium longum*: ATCC 55813 to 55818, with 55817 identified as having the strongest acid tolerance, as shown in the “Acid Tolerance Counts Decreased” section of Table IV. Of particular interest, in Tables 2 and 3 of the present specification, which show results of acid tolerance tests to determine long term survivability in an acidic environment, it is illustrated that the FERM BP-7787 strain of the present invention has far superior acid tolerance characteristics when compared to ATCC 55817. In particular, ATCC 55817 has a survival rate of 0.01% after attaining pH of about 4.4 in a milk base medium, and storing at 10°C for two weeks, whereas the FERM BP-7787 has a survival rate of 50% or higher, which is required in claims 1, 3, and 4. This survival rate is significantly higher than that of the ATCC 55817 strain in Yang.

Accordingly, contrary to Examiner’s assumption, the Yang microorganisms do not possess the same milk base medium survival rate characteristics as the presently claimed microorganism. Further, the differences in the characteristics of FERM BP-7787 and the microorganisms disclosed in Yang, as shown with the low pH milk base medium survivability tests, are significant. Thus, the microorganisms disclosed in Yang are not all likely to inherently possess, or make obvious, the characteristics of Applicants' claimed FERM BP-7787. Therefore, like Kawashima and Martin, not only does Yang fail to teach the *Bifidobacterium longum* FERM BP-7787, Examiner has failed to establish a *prima facie* case of obviousness based on the Yang disclosure.

For all of the above reasons, the references cited by the examiner do not anticipate the Applicants' claims, nor do the references render the claims obvious. Applicants thus



respectfully submit that independent claims 1, 3, and 4 are allowable over the cited references, such claims being in condition for allowance.

### **Conclusion**

As a result of the remarks given herein, Applicants submit that the rejection of the pending claims has been overcome. Therefore, Applicants respectfully submit that this case is in condition for allowance and request allowance of the pending claims.

If Examiner believes any detailed language of the claims requires further discussion, Examiner is respectfully asked to telephone the undersigned attorney so that the matter may be promptly resolved. Applicants also have submitted all fees believed to be necessary herewith. Should any additional fees or surcharges be deemed necessary, Examiner has authorization to charge fees or credit any overpayment to Deposit Account No. 23-3000.

Respectfully submitted,  
WOOD, HERRON & EVANS, L.L.P.

By /Randall S. Jackson, Jr./  
Randall S. Jackson, Jr.  
Reg. 48,248

2700 Carew Tower  
Cincinnati, Ohio 45202  
(513) 241-2324  
FAX (513) 241-6234